

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MINNESOTA

IN RE: Stryker Rejuvenate and ABG II Hip)
Implant Products Liability Litigation)
_____)

MDL No. 13-2441 (DWF/FLN)

This Document Relates to:)
)

Charlotte D. Smith and Tommy E.)
Smith, wife and husband,)
)

Plaintiffs,)

C O M P L A I N T
(Tort - Product Liability)

vs. Civil No. 0:14-cv-275)
)

JURY TRIAL DEMANDED

HOWMEDICA OSTEONICS)
CORPORATION, a New Jersey)
corporation d/b/a STRYKER)
ORTHOPAEDICS; STRYKER)
CORPORATION, a Michigan corporation;)
and STRYKER SALES CORPORATION,)
)

Defendants.)
_____)

PLAINTIFFS, Charlotte D Smith and Tommy E. Smith, wife and husband, by
and through counsel, for their cause of action against Defendants, allege, as follows:

I. INTRODUCTION

1. This is an action for personal injury, statutory, compensatory, and punitive damages due to Plaintiff as a result of Defendants' non-disclosure of risks associated with their medical device Rejuvenate Hip System as well as their gross exaggeration of the purported benefits to be enjoyed by implant recipients of this system over other hip prostheses and the over-promotion of this system as well as being based on the system's inadequate design and manufacture as well as

Defendants' express warranties regarding the Rejuvenate Hip System.

II. JURISDICTION AND VENUE

_____2. This is an action for damages that exceed \$75,000 exclusive of interest and costs, the statutory minimum jurisdiction of this court pursuant to diversity of citizenship.

3. At all times pertinent to this action, Plaintiffs were residents of the State of Arizona residing in Green Valley, Pima County, Arizona.

4. Venue for this action is proper with the Tucson Division of the United States District Court for the District of Arizona.

5. Defendant, Howmedica Osteonics Corporation, (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS, is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey 07430 and conducts business throughout the United States including in the State of Arizona. Defendants Stryker Corporation and Stryker Sales Corporation are corporations organized and existing under the laws of the State of Michigan having their principal place of business at 4100 East Milhare Avenue, Kalamazoo, MI, 49001.

6. Jurisdiction is proper and appropriate pursuant to 28 U.S.C. §1332 based on the diversity of citizenship between the parties.

7. While venue is proper in the Tucson Division of the United States District Court for the District of Arizona based on Plaintiffs' residence there, the Judicial Panel on Multi-District Litigation ("JPML") has by previous order dated June 12, 2013 pursuant to 28 U.S.C. §1407 centralized and transferred all pending and subsequently filed actions relating to the failure of the Rejuvenate Hip Systems to the United States District Court for the District of Minnesota, and has

designated said centralized proceeding as In Re: Stryker Rejuvenate and ABGII Hip Implant Products Liability Litigation, MDL No. 2441, which is assigned to the Honorable Donovan W. Frank. Pursuant to this Court's Pretrial Order No. 4 dated October 3, 2013, direct filing of related actions is allowed for the purpose of consolidation of discovery and related pretrial proceedings, and pursuant to paragraph 5 of said Order, reference is hereby made to same.

III. THE PRODUCT

8. At all times material hereto, Defendant HOWMEDICA d/b/a Stryker Orthopaedics, Stryker Corporation and Stryker Sales Corporation (hereinafter collectively referred to as "Defendants") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product marketed under the name "The Rejuvenate System" (hereinafter "Rejuvenate System" or "Defective Device"), either directly or indirectly, to members of the general public within the State of Arizona and elsewhere including Plaintiff Charlotte D. Smith.

9. Defendants' Defective Device, after having been placed into the stream of interstate commerce by Defendants, was implanted in Plaintiff Charlotte D. Smith's left hip on December 14, 2009.

10. As a direct and proximate result of Defendants placing the Defective Product into the stream of commerce, Plaintiff Charlotte D. Smith has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, as well as other related damages.

11. On June 3, 2008, Defendants received FDA clearance to sell their Rejuvenate System

in the United States. Sometime during the first week of July 2012, Defendants issued a voluntary worldwide recall of both the Rejuvenate and ABG II hip replacement systems.

12. The Rejuvenate System is a modular hip replacement prosthesis. Were it not defective, it would be indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis.

13. Unlike most prosthetic hip implants, the Rejuvenate System is an artificial hip replacement device consisting of two basic components: a chrome cobalt neck that is inserted into a titanium stem. The System can be used with any number of bearing surface components comprised of the ball (or artificial femoral head) and an acetabular cup (or socket).

14. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. This alloy was designed and patented by Defendants and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. Defendants claim in their promotional materials for the Rejuvenate System that their alloy is both stronger and less rigid than other titanium alloys. They also claim that the particular titanium alloy has been tested and proven by Defendants to resist the effects of corrosion and fretting.

15. At all times material hereto, the Rejuvenate stems and necks implanted in Plaintiff Charlotte D. Smith were designed, manufactured, marketed, distributed and/or supplied by Defendants.

16. After the implantation of the Defective Devices, Plaintiff Charlotte D. Smith began to experience significant discomfort in the area of her Defective Devices.

17. Original diagnostic work-up in approximately March 2011 reflected loosening in the

cup area of Plaintiff Charlotte D. Smith's prosthesis which said area was replaced on March 16, 2011. Thereafter, Plaintiff Charlotte D. Smith again began to experience severe pain in the area of her prosthesis. Diagnostic work-up at that time revealed the absence of device loosening, infection, malposition or any other explanation for Plaintiff's symptoms.

18. Further diagnostic work-up revealed that the Plaintiff's cobalt levels were elevated and there existed the probability of corrosion and fretting of the Rejuvenate hip components.

19. Based upon these findings and in light of Plaintiff's worsening symptoms, she was taken back for revision surgery on her left hip on May 22, 2013, where it was noted that '[u]pon entering to the subfascial layer, she was noted to have an extensive adverse local tissue reaction, which has permeated from the posterior joint and extending around the trochanter and into the portion of the abductors..She did have some necrotic appearing bone in the proximal anterior portion of the femur.'

20. At the time of filing this Complaint, Plaintiff may be required to continue to undergo rehabilitation, and is unsure what sequelae she will be forced to endure for the remainder of her life as a result of the Defective Product.

IV. THE STRYKER REJUVENATE HISTORY

21. In February 2009, Defendants released their Rejuvenate Modular Primary Hip System, which was the latest evolution in the companies' OmniFit and Secure-Fit Hip systems, and which was approved for market pursuant to §510(k) of the Food, Drug and Cosmetics Act by the FDA on June 3, 2008. The Rejuvenate Modular hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on September 13, 2007.

22. According to Defendants' materials, the Rejuvenate Modular Primary Hip System

was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version and offset, the Rejuvenate Modular Primary Hip System was marketed to enable surgeons to better personalize the implant to the patient's unique anatomy.

23. The system is comprised of separate femoral stem and neck components and offers a variety of sizing options intra-operatively. The benefit, according to Defendants, was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of a patient's hip replacement.

24. The Rejuvenate System combines the material characteristics of TMZF (Ti-12-Mo-6Zn-2Fe) with a plasma sprayed coating of commercially pure Ti and PureFix HA for the stem and CoCr for the neck. Defendants affirmatively claimed that laboratory testing demonstrated the compatibility of these materials without concern for fretting and corrosion.

25. In spite of Defendants' claim, this material combination has been reported to cause corrosion. Since the 1980's medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions. In its marketing and sale of the Defective Device, Defendants represented and expressly warranted that their proprietary materials alleviate this problem.

26. Defendants hold two patents for modular implant devices. Currently, Defendants have a pending application to patent a modular hip prosthesis similar to the Rejuvenate System.

V. URGENT FIELD SAFETY NOTICES AND RECALLS

27. In April 2012, Defendants issued an Urgent Field Safety Notice to surgeons and hospitals in the United States.

28. As a part of this notice, Defendants acknowledged that they had received reports of device failure due to heavy metal contamination. The notice specifically referred to failures at the taper neck junction between the neck and stem due to corrosion and fretting.

29. The corrosion and fretting described in the notice was exactly the same failure mechanism that Defendants had warranted would not occur because of the Rejuvenate's design and composition. It was also exactly the same failure mechanism that the medical and scientific community had been studying and documenting in modular device design since the 1990's.

30. The notice went on to describe symptoms and findings identical to those experienced by Plaintiff, and documented in her revision surgeries.

31. Among those deleterious medical concerns specifically mentioned in the notice were tissue necrosis, metallosis, adverse soft tissue reaction, and pseudotumor formation.

32. Almost immediately following the notice, Defendants issued a voluntary recall of the Stryker Rejuvenate and ABG II in Canada. In the recall notice, Defendants stated that they were amending the "Instructions for Use" for the device to include warnings which demonstrate Defendants were on notice of the issues described in the notice discussed above.

33. Finally, in the first week of July 2012, Defendants issued a voluntary recall of all Stryker Rejuvenate and ABG II systems. As part of the recall notice, Defendants once again cited reports of device failure due to heavy metal fretting and corrosion.

VI. THE FEDERAL REQUIREMENTS

34. Federal regulation states, "Recall means a firm's removal or correction of a

marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.” *See*, 21 CFR §7.3(g).

35. Another federal regulation states: “Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. *Id.*, at §7.3(m).

36. Additionally, federal regulations provide, “Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.” *Id.*

37. Defendants classified their recall as Class II, which acknowledges by definition that Defendants’ device was in violation of federal law, and that had Defendants not “voluntarily” recalled it would have been subject to the initiation of legal action by the government and/or seizure of unsold devices.

38. By federal statute, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. 21 U.S.C. §351.

39. By federal statute, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. 21 U.S.C. §352.

40. Under federal law, manufacturers are required to comply with FDA regulation of

medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk of health hazard posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S. C. §360(i).

41. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to the FDA within thirty days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction were to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See*, 21 CFR §803.52.

42. By federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *Id.* at §803.52.

43. By federal regulation, manufacturers must report to the FDA in five business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. *Id.* at §803.53.

44. Pursuant to federal regulation, device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. 21 CFR §806.

45. According to federal regulation, manufacturers must comply with specific quality system requirements promulgated by the FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are

also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See* 21 CFR §820.

46. Pursuant to federal regulation, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. Federal regulations require that: “A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence or anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

47. Specifically, it is believed that with respect to the Rejuvenate and ABG II Systems, Defendants failed to timely report adverse events, failed to timely conduct failure investigations and analyses, failed to timely report any and all information concerning product failures and corrections, failed to timely and fully inform the FDA of unanticipated adverse events, increases in the incidence of adverse events, or and failed to report device failures necessitating labeling, manufacturing or device modification, failed to conduct necessary design validation, and sold a misbranded and adulterated product.

VII. CAUSES OF ACTION

COUNT ONE

PRODUCTS LIABILITY - DEFECTIVE DESIGN

48. Plaintiff reasserts and realleges all matters set forth in the paragraphs hereinabove, and by reference incorporates same herein.

49. This is an action based upon design defect against Defendants.

50. Defendants' Rejuvenate implant is designed in such a way that when used as intended causes serious, permanent and devastating damage to patients in whom it is implanted. The damage and mechanism of injury have been previously described hereinabove.

51. Defendants' Rejuvenate Implants do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

52. The risks of implanting Defendants Rejuvenate implant outweigh the benefits that may be realized from its implantation.

53. The Rejuvenate device implanted in Plaintiff's left hip was defectively designed.

54. The design defect in Defendants' Rejuvenate implants caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, all of which damage and losses will continue in the future.

COUNT TWO

STRICT LIABILITY - FAILURE TO WARN

55. Plaintiffs reassert and reallege all matters set forth in the preceding paragraphs as if same were set forth at length herein and incorporate same by reference herein.

56. The Rejuvenate device implanted in Plaintiff contained no warnings or, in the alternative, inadequate warnings as to the risk that the product could and likely would corrode and fret and cause significant heavy metal toxicity.

57. The warnings that accompanied the Rejuvenate implant failed to provide that level of information that an ordinary consumer would expect when using the Rejuvenate device in a

manner reasonably foreseeable to the Defendants.

58. Had Plaintiff received a proper or adequate warning as to the risks associated with using the Rejuvenate devices, she would not have allowed the device to have been implanted into her body.

59. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Rejuvenate device, he would not have recommended the device, would have used an alternate device or, at a minimum, would have provided Plaintiff with adequate warning and obtained her informed consent before implanting the device into Plaintiff's left and right hips. As stated above, had Plaintiff received an adequate warning, she would not have agreed to have the Rejuvenates device implanted in her.

60. The failure to warn of the Rejuvenate's risks caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, all of which damage and losses will continue in the future.

COUNT THREE

MANUFACTURING DEFECT

61. Plaintiffs reassert and reallege all matter set forth in the paragraphs above as if set forth at length herein and incorporate same by reference herein.

62. This is an action based on a manufacturing defect against the Defendants.

63. The Rejuvenate hip implant is designed for implantation into the human body and to last fifteen or more years with the femoral component intended to last for the patient's lifetime. It

is also designed with the intention of being compatible with human tissue and bone.

64. The Rejuvenate hip implanted in Plaintiff failed and was removed in approximately two years from its implantation.

65. The Rejuvenate hip implant installed in Plaintiff's left hip was not compatible with human tissue and bone. Through the process of fretting and corrosion, said device released heavy metals into Plaintiff's body causing severe and permanent destruction of bone and tissue. Defendants failed to manufacture the product in a manner which prevented fretting and corrosion and, in fact, manufactured the product such that through its regular and intended use it exhibited fretting and corrosion.

66. As such, the Rejuvenate implant installed in Plaintiff's hip contained a manufacturing defect.

67. The manufacturing defect in the Rejuvenate hip implanted in Plaintiff caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, all of which damage and losses will continue in the future.

COUNT FOUR

BREACH OF EXPRESS WARRANTY

68. Plaintiffs reassert and reallege all matters set forth in the paragraphs above as if same were set forth at length herein and by reference incorporate same herein.

69. Through their public statements, their descriptions of the Rejuvenate system, and their promises relating to the Rejuvenate system, Defendants expressly warranted, among other

things, that the Rejuvenate system was efficacious and safe for its intended use; was designed and constructed of materials that would not fret or corrode; would last longer than competing hip prosthetic devices; and was more suitable for mitigating the need for subsequent revision surgery given its purported longevity.

70. The foregoing warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Rejuvenate System, but which contained material misrepresentations and utterly failed to warn of the risks of the Rejuvenate system; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the Rejuvenate System and downplaying the risks associated with the Rejuvenate system; (iv) false and misleading written information supplied by Defendants.

71. The most prominent representation made by Defendants was on their website where they expressly warranted that the design, testing and materials utilized in the Rejuvenate system would not fret or corrode.

72. Plaintiffs further allege that all of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiffs' reasonable belief that these materials shall be produced by Defendants as part of their mandatory disclosures and be made of record once Plaintiffs are afforded the opportunity to conduct discovery should same not be voluntarily disclosed.

73. At the time Defendants made these express warranties, Defendants knew the purpose for which the Rejuvenate system was to be used and warranted it to be in all respects safe and proper for such purpose.

74. Defendants, their agents, and/or employees drafted the documents and/or made the statements upon which these warranty claims are based, and, in so doing, defined the terms of those warranties.

75. The Rejuvenate system does not conform to Defendants' representations in that it is not safe, efficacious and said system produces serious deleterious health issues.

76. As such, the Rejuvenate System did not conform to Defendants' promises, descriptions or affirmations of fact and was not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such devices are used.

77. Defendants' breach of their express warranties caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, all of which damage and losses will continue in the future.

COUNT FIVE

BREACH OF IMPLIED WARRANTY - FITNESS FOR A PARTICULAR PURPOSE

78. Plaintiffs reassert and reallege all matters set forth in the paragraphs above as if same were set forth at length herein and by reference incorporate same herein.

79. A.R.S. §47-2315 of the Arizona Uniform Commercial Code provides:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under section 47-2316 an implied warranty that the goods shall be fit for such purpose.

80. Defendants sold the Rejuvenate system, either directly or indirectly, to Plaintiff.

81. At the time of such sale, Defendants had reason to know that said system would be implanted in Plaintiff's body and employed as a prosthetic device in a safe and efficacious manner.

82. As the manufacturer of medical devices – in particular orthopaedic prostheses – Defendants were in a superior position to understand the requirements for the functionality, safety and efficiency of the devices they sold.

83. Plaintiff, as a lay person, relied on Defendants' expertise, skill and judgment in selecting the Rejuvenate system to be implanted in her body.

84. Because of its high propensity for fretting and corrosion, thus causing heavy metals to be released into the blood of those implanted with the Rejuvenate system thereby causing degradation of tissue and bone, the Rejuvenate system was not fit for the particular purpose for which it was sold by Defendants and purchased by Plaintiff, to wit: prosthetic devices employed and implanted in humans.

85. As such, Defendants breached their implied warranty of fitness for particular purpose as set forth in A.R.S. §47-2315.

86. Defendants' breach of their implied warranty caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, all of which damage and losses will continue in the future.

COUNT SIX

NEGLIGENCE

87. Plaintiffs reassert and reallege all matters set forth in the paragraphs above as if same were set forth at length herein, and by reference incorporate same herein.

88 Defendants had a duty to exercise reasonable care in the designing, testing, developing, manufacturing labeling, marketing, distribution and selling of the Rejuvenate system, including a duty to ensure that users, such as Plaintiff, did not suffer unreasonable adverse side effects.

89. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

- a. Failing to properly and thoroughly test the Rejuvenate system before releasing it onto the market;

- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of the Rejuvenate system;

- c. failing to conduct sufficient post-market testing and surveillance of the Rejuvenate system;

- d. designing, manufacturing, marketing, advertising, distributing, and selling the Rejuvenate system to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks associated with the Rejuvenate system;

- e. failing to exercise due care when advertising and promoting the Rejuvenate system;

- f. negligently continuing to manufacture, market, advertise, and distribute the Rejuvenate system without adequately warning the general public and Plaintiff in particular of potential adverse side effects after Defendants knew or should have known of the possibility and

probability of such adverse events.

90. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care.

91. As a direct and proximate consequence of Defendants' failure to adequately warn or other acts, omissions and/or misrepresentations described herein, Plaintiff developed severe and permanent injuries, including metallosis and necrosis of the bone and tissue as well as infection, pain and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions.

92. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in accordance with the laws of the State of Arizona so as to punish Defendants and deter them from similar conduct in the future.

COUNT SEVEN

ARIZONA CONSUMER FRAUD ACT (A.R.S. §44-1521 et seq.)

93. Plaintiff reasserts and realleges all matters set forth in the paragraphs above as if same were set forth at length herein and by reference incorporates same herein.

94. Hip prostheses such as the Rejuvenate system are "merchandise" as that term is defined by A.R.S. §44-1521 et seq. ("the Act").

95. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and/or otherwise released the Rejuvenate system into the stream of commerce, either directly or indirectly through third parties or related entities.

96. Defendants knew or should have known that the use of implantation of the Rejuvenate system caused serious and life threatening injuries but failed to warn physicians, the public including Plaintiff, and the FDA of same.

97. Defendants knew that all previous attempts at developing modular hip prosthetic systems such as the Rejuvenate system had failed as the result of fretting and corrosion and affirmatively represented to the general public including plaintiff, orthopaedic surgeons and the FDA that, based upon their patented alloy, the Rejuvenate system did not nor would not include the risk of fretting and corrosion that had plagued earlier failed attempts at creating workable and usable modular hip prosthetic systems. Said representations were made without sufficient testing or clinical experience, and were false. Defendants' representations were made with the purpose of increasing sales of its merchandise, and touting its purported benefits and reliability as being superior to other products on the market produced and sold by other manufacturers. Defendants knew or should have known that their representations were false and therefor misleading. Defendants knew that their representations would be relied upon by the public in general and Plaintiff in particular and were made with the intention that consumers would rely on same.

98. In violation of the Act, Defendants made untrue, deceptive and/or misleading representations of material facts to and omitted and/or concealed material facts from Plaintiff in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety of the Rejuvenate system. Moreover, Defendants down-played and/or understated, and/or failed to reveal the serious nature of the risks associated with the Rejuvenate system in order to increase the sales of the Rejuvenate system based on artifice.

99. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, the medical community and consumers, including Plaintiff, would rely on Defendants' statements and/or omissions.

100. Defendants knew of the growing public acceptance of its misinformation and misrepresentations regarding the safety and efficacy of the Rejuvenate system but remained silent because Defendants' appetite for significant future profits far outweighed its concern for the health and safety of Plaintiff and consumers in general.

101. Plaintiff's orthopaedic physician implanted Plaintiff with the Rejuvenate systems primarily for Plaintiff's personal and family reasons, and Plaintiff has suffered ascertainable losses of money as a result of Defendants' use or employment of the methods, acts, or practices alleged herein.

102. The aforesaid promotion and release of the Rejuvenate system into the stream of commerce constitutes unconscionable commercial practices, deception, false pretense, misrepresentation, and/or knowing concealment, suppressions or omissions in connection with the sale or advertisement of such merchandise or services by Defendants in violation of the Arizona Consumer Fraud Act, A.R.S. §44-1521, et seq.

103. Defendants concealed, omitted, or minimized the side effects of the Rejuvenate system and/or provided misinformation about the adverse reactions, risks, and potential harm from the Rejuvenate system and succeeded in persuading consumers to purchase and have implanted the Rejuvenate system despite the lack of safety and the risk of adverse medical reactions.

104. Defendants' practice of promoting and marketing the Rejuvenate system created

and reinforced a false impression as to the safety of the Rejuvenate system, thereby placing consumers such as Plaintiff at risk of serious and potential significantly deleterious complications from said system.

105. The Rejuvenate system lacked appropriate warnings, and the packaging and labels employed by Defendants were misleading, inaccurate, incomplete, and/or untimely.

106. Defendants violated their post-manufacture duties to warn which arose when Defendants knew, or with reasonable care should have known that the Rejuvenate system was injurious.

107. At the time when consumers purchased and were implanted with the Rejuvenate system, Defendants intended that others would rely upon concealment, suppression or omission of the risks of being implanted with the Rejuvenate system..

108. Defendants actions in connection with manufacturing, distributing, and marketing of the Rejuvenate system as set forth herein evidences a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices in violation of the Arizona Consumer Fraud Act, A.R.S. §44-1521 et seq.

109. As a proximate result of the Defendants' consumer fraud set forth above, Plaintiff has purchased unsafe products and incurred and continues to incur monetary expense at peril to herself and members of her household by having been implanted with a Rejuvenate system and thereby suffering an increased risk of harm as previously set forth herein.

COUNT EIGHT

LOSS OF CONSORTIUM - TOMMY E. SMITH

110. Plaintiffs reassert and reallege all matter set forth in the preceding paragraphs as if

set forth at length herein, and incorporate same herein.

111. At all times pertinent hereto, Plaintiff Tommy E. Smith was married to Plaintiff Charlotte D. Smith. As a direct and proximate result of the injuries and damages sustained by his wife, Charlotte D. Smith, Tommy E. Smith has suffered the loss of his wife's care, comfort, society and affections.

RELIEF REQUESTED

_____**WHEREFORE**, Plaintiff demands judgment against Defendants, as follows:

- A. Awarding Plaintiffs compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiffs for all damages they have sustained;
- B. Awarding Plaintiff treble damages against Defendants so as to fairly and completely compensate Plaintiff for all damages, and to deter similar wrongful conduct in the future;
- C. Awarding Plaintiffs punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter similar wrongful conduct in the future.
- D. Awarding Plaintiffs costs and disbursements, cost of investigations, attorneys' fees and all such other relief available under Arizona law;
- E. Awarding the costs incurred in this action to be taxed against Defendants;
- F. Awarding such other and further relief as is just and reasonable in the premises.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all issues so triable in this action.

By:/s/Gary S. Grynke
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Sarah J. Showard
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